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Kurt-Reiner Geiss

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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/665,394	Applicant(s) GEISS, KURT-REINER	
	Examiner Snigdha Maewall	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 15, 17-19 and 23-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 15, 17-19 and 23-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/12/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

1. Receipt of Applicant's arguments/Remarks and amended claims filed on 06/19/09 is acknowledged.

Receipt of IDS and Declaration filed on 06/12/09 is also acknowledged.

Claims 1-13, 16 and 20-22 have been cancelled and new claims 37 to 46 have been added in this application.

Claims **14-15, 17-19 and 23-46** are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 37-9 and 40- 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40-42 and claim 46 recite the limitation "greater" which makes the claim indefinite. The term greater is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 37 to 39 recite the limitation "high" which makes the claim indefinite. The term high is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The phrase "short term and long term" makes the claims indefinite because metes and bounds of claims are not defined.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims **14-15, 17-19 and 23-46** are rejected under 35 U.S.C. 103(a) as being unpatentable over Buchholz et al. (US Patent No. 6,514,973) in view of Lang et al. (US Pub. No. 2003/0161861 A1).

Buchholz et al. discloses that oral supplementation with 200 to 300 mg of phosphatidylserines per day for 2 to 6 months improves brain metabolism and benefits cognitive functions such as memory, thinking, learning, and the ability to concentrate especially in aging people and in patients with certain neurological and pathopsychological conditions (see column 2, lines 20-32).

The reference also discloses the effectiveness of phosphatidylserines in the treatment of senile dementia, Parkinson's disease epilepsy, depression, and age-associated memory impairment has also been demonstrated in several studies. (See column 2, lines 27-30). Buchholz et al. further teach that phosphatidyl serine provides metabolic support to a wide range of brain functions. Phosphatidyl serine stimulates glucose metabolism in the brain and also increases the number of neurotransmitter receptor sites. (See column 2, lines 32-35). Buchholz et al. discloses that the disclosed compound (which includes phosphatidyl serine) is suitable for food or food supplement composition (see column 6, lines 55-56). The invention also relates to food or food supplement compositions comprising one or more active ingredients according to claim 1. (It is to be noted that claim 1 comprises phosphatidyl serine).

The reference further discloses that food compositions comprise one or more active ingredients and one or more nutritional substances. The nutritional substances encompass all materials which are suited for consumption both by animals and/or by human beings, e.g. vitamins and provitamins thereof, fats, minerals or amino acids. Nutritional substances, which can be part of the inventive food compositions are e.g. materials, which are derived substantially from a single natural source such as sugar, unsweetened juice, nectar or puree from a single species of plant, such as unsweetened apple juice (including a blend of different varieties of apple juice), grapefruit juice, orange juice, apple sauce, apricot nectar, tomato juice, tomato sauce, tomato puree, grain plants of a single species and materials produced from grain plants of a single species, such as corn syrup, rye flour, wheat flour or oat bran.

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The food compositions are e.g. of food preparations such as breakfast foods, e.g. prepared cereals, toaster pastries, and breakfast drink mixes, infant formulas, dietary supplements, complete diet formulas, and weight-loss preparations, such as weight-loss drinks and weight-loss bars. The nutritional substances include all edible combinations of carbohydrates, lipids, proteins, inorganic elements, trace elements, vitamins, water, and active metabolites of plants and animals. (see column 5, lines 40-65 and column 6, lines 9-13). Buchholz et al. further teach that the specific dose of food or food supplement for each patient depends on a wide variety of factors, for example on the activity of the specific compounds employed, on the age, bodyweight, general state of health, sex, on the diet, the time and route of administration (see column 6, lines 45-50).

Although Buchholz et al. teach that phosphatidyl serine stimulates glucose metabolism in the brain and also increases the number of neurotransmitter receptor sites. (See column 2, lines 32-35).

Buchholz et al. do not explicitly teach role of carbohydrate in improving cognitive function of brain.

Lang et al. discloses a cereal product comprising starch, which improves cognitive performances, in particular memory retention, attention concentration, vigilance and /or mental well being in people and particularly in a child and an adolescent. Table 1 on page 2 discloses a composition comprising spaghetti, kidney beans potatoes white bread and whole meal bread etc. Table 8 depicts carbohydrates, proteins and lipids.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate carbohydrates in the reference of Buchholz et al. since Lang et al. teach that food products containing carbohydrates such as starch improve cognitive performances. One skilled in the art would have been motivated to incorporate starch in the teachings of Buchholz because Buchholz teaches that Phosphatidyl serine stimulates glucose metabolism in the brain and also increases the number of neurotransmitter receptor sites. (See column 2, lines 32-35) and Lang et al. teaches that starch improves cognitive performances. Since starch is known to breakdown into glucose during metabolism, one skilled in the art would have reasonable expectation of success in combining starch as taught by Lang et al. and phosphatidylserine as taught by Buchholz et al. in improving cognitive performances.

With respect to various amounts and percentages of various components, it is the position of the examiner that optimization of such parameters would have been within the purview of a skilled artisan at the time the invention was made by doing experimental manipulations. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955).

Response to Arguments

6. Applicant's arguments filed 06/12/09 have been fully considered but they are not persuasive.

Applicant argues that the teachings of cited references do not make the claimed invention obvious. Applicant argues that Buchholz does not teach the role of carbohydrates in improving cognitive function and no correlation has been disclosed between phosphatidyl serine and glucose. Applicant argues that instant invention does not deal with stimulation of glucose metabolism and Buchholz and Lang do not disclose analogous composition.

Applicant's arguments are not persuasive because Buchholz teaches phosphatidyl serine increases glucose metabolism and secondary reference teaches starch in improving cognitive performances. While it is true that the instant claims do not recite the limitation of increasing glucose metabolism in brain however, by this teaching one of ordinary skill would envisage use of starch in cerebral activity. Regarding Lang's teachings, it is the position of the Examiner that Lang explicitly teaches improvement in cognitive performances, therefore the assertion that Lang is not analogous in the teachings is without any basis.

Applicant argues that Lang teaches low digestible starches, in response to this argument the Examiner points out that the instant claims do not define any specific carbohydrate. Claim 1 lacks any specific source of phosphatidyl serine or any specific category of carbohydrate. Claims as recited do not enumerate various carbohydrates.

Applicants allege that based on the teachings of prior art and in view of various references cited, there is unpredictability in producing the claimed food product comprising phosphatidyl serine and carbohydrate which improves cognitive performances. Applicant argues that in view of declaration, the combination of the two

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prior art would not have provided unexpected results. Applicant's arguments are not persuasive and responses to these arguments which are in light of declaration have been presented below.

Response to Declaration

7. The declaration under 37 CFR 1.132 filed on 06/12/09 is insufficient to overcome the rejection of claims based upon the rejections as set forth in the last Office action because:

Applicant assert that the inventor has discovered unexpected functional relationship between phosphatidyl serine and simple carbohydrates and have provided evidence of greater than expected results in treating cognitive performance by providing the food bar of claimed invention comprising phosphatidyl serine and carbohydrate. Applicants have demonstrated various data.

Applicant's declaration is not persuasive because of several reasons as discussed below:

First, applicants contend unexpected results with simple carbohydrates but the claims as recited do not recite the limitation of being simple, Claim 1 generically recites carbohydrates. Additionally, the declaration provides data for only 200 mg of phosphatidyl serine and 20 g of carbohydrate whereas the claims as recited has the limitation of minimum of 100 mg of phosphatidyl serine and minimum of 10 g of carbohydrate, as such no data has been provided for amounts which are below 200 mg of phosphatidyl serine and less than 20 g of carbohydrate. The declaration does not

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provide any cognitive performance for amount such as 100 mg of phosphatidyl serine or 10 g of carbohydrate. Furthermore, carbohydrate is a very broad generic term which encompasses starches of various glycemic index. One of ordinary skill would expect varying extent of cognitive performance due to different carbohydrates with varied glycemic index. Applicants have only provided results with generic carbohydrate with no mention of any specific component with specific glycemic index.

Applicants themselves state on page 15 of the response that certain phosphatidyl serine did not show any cognitive performance and thus there exists unpredictability in cognitive improvement. If such is the case, (which applicants assert with regard to Buchholz and Lang), then applicants own invention is unpredictable because claim 1 does not recite any specific source of phosphatidyl serine or any specific carbohydrate. Prior art by Buchholz explicitly teaches cognitive improvements due to phosphatidyl serine and Lang also recognizes carbohydrates role in cognitive performances, the claimed invention is therefore obvious over the teachings of prior art.

Applicant consistently argues synergic affect of phosphatidyl serine and carbohydrate, however, review of table 3, does not show any difference between pre and post carbohydrate levels. By definition, synergistic affect means that there is some affect associated with the compound by itself, however the graph shows two equal bars for carbohydrate as such applicant's argument about synergistic affect is not persuasive.

The claims do not recite the synergic effect for phosphatidyl serine and carbohydrate, as such the scope of claims do not commensurate with the scope of declaration.

Review of the graph on page 6 of declaration shows standard deviation which is so high that one cannot determine the statistical significance let alone the palatable significance. The results do not appear to show even **an additive effect**. The improvement in cognitive performance is not to an unexpected degree.

Applicant declares on page 6 under result section, that there was no difference in cognitive performance in pre and post tests with PS or carbohydrate once consumed individually. This comparison is not direct comparison with the prior art's teachings which teaches that PS increases cognitive performance as disclosed by Buchholz and Carbohydrates increase cognitive performance as disclosed by Lang et al. Additionally, the results on page 5-6 show difference in no. of subjects who consumed PS and carbohydrates. Results from only 2 subjects consuming PS do not provide any statistical significance. The rationale behind having 10 subjects consuming carbohydrate and only 2 subjects consuming PS is not clear to the Examiner. The declaration recognizes synergistic effect of PS and carbohydrate, however there is no Control to compare with. Prior art explicitly recognizes PS to improve cognitive performance and carbohydrate to improve cognitive performance.

The results disclosed on page 3 attest applicants own invention, however the results are obvious in view of the teachings of prior art because Buchholz teaches

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cognitive improvement due to PS and Lang teaches due to carbohydrate. The claimed invention therefore does not provide unexpected result.

Instant claims recite the minimum effective amount for improving cognitive performance to be 100 mg, the declaration on page 6, recognizes that there is no difference in results in pre and post tests, it is unclear to the Examiner as to how a nutritional bar with 100 mg PS will improve cognitive performance when the one with 200mg PS, does not show any difference in cognitive performance compared to one without any PS.

In light of the above, it is the position of the examiner that the declaration is insufficient to overcome the rejection.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612